

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY,)	
GENEOHM SCIENCES CANADA, INC.)	
and HANDYLAB, INC.,)	
)	
Plaintiffs,)	
)	C.A. No. <u>19-1126-LPS</u>
v.)	
)	DEMAND FOR JURY TRIAL
NEUMODX MOLECULAR, INC.,)	
)	FILED UNDER SEAL
Defendant.)	

**DEFENDANT NEUMODX MOLECULAR, INC.'S AMENDED
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS'
FIRST AMENDED AND SUPPLEMENTAL COMPLAINT**

Defendant NeuMoDx Molecular, Inc. ("NeuMoDx") answers Plaintiffs Becton, Dickinson and Company, GeneOhm Sciences Canada, Inc. (collectively "BD"), and HandyLab, Inc. ("HandyLab" and collectively with BD, "Plaintiffs") First Amended and Supplemental Complaint and hereby allege as follows:

NATURE OF THE ACTION

1. No response is necessary for this statement.
2. NeuMoDx admits that Plaintiffs brought the present action, but denies that it has infringed any of Plaintiff's patent rights, including the Asserted Patents, or that Plaintiffs are entitled to any relief.

THE PARTIES

3. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 3, and therefore denies same leaving Plaintiffs to their proofs.
4. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 4, and therefore denies same leaving Plaintiffs to their proofs.
5. Admitted.

JURISDICTION AND VENUE

6. Paragraph 6 states a legal conclusion and therefore no response is required.

NeuMoDx does not dispute subject matter jurisdiction.

7. Admitted in part and denied in part. NeuMoDx admits that this Court may exercise personal jurisdiction over NeuMoDx. However, NeuMoDx denies the remaining allegations in paragraph 7.

8. Admitted in part and denied in part. NeuMoDx admits that venue is proper in this District. However, NeuMoDx denies the remaining allegations in paragraph 8, including that Delaware is the most convenient forum for litigating this action.

FACTUAL ALLEGATIONS

Background

9. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 9, and therefore denies same leaving Plaintiffs to their proofs.

10. Admitted.

11. Exhibits 7 and 8 speak for themselves and therefore no response is required on allegations based upon those documents. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 11, and therefore denies same leaving Plaintiffs to their proofs.

12. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 12, and therefore denies same leaving Plaintiffs to their proofs.

13. NeuMoDx admits that Jeff Williams founded Molecular Systems Corp. in 2012, and that Molecular Systems Corp. changed its name to NeuMoDx. NeuMoDx admits that Sundaresh Brahmasandra served as Vice President of Research and Development Assay

Development at BD after the HandyLab acquisition, but that Brahmasandra joined NeuMoDx as President in 2012 only after requesting and obtaining express written permission from BD. NeuMoDx admits that Williams and Brahamsandra are each named inventors on some of patents asserted in the Complaint, and are now aware of the Asserted Patents. NeuMoDx denies the remaining allegations in paragraph 13.

14. Denied.

15. NeuMoDx admits that it commissioned a review of patents no later than 2017 before making, using, selling or offering to sell NeuMoDx's molecular diagnostic products, which information was provided to BD on a confidential basis solely for the purpose of BD's consideration of NeuMoDx when NeuMoDx was being offered for sale, and which public disclosure by BD violates that obligation of confidentiality. NeuMoDx denies the remaining allegations in paragraph 15.

16. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 16, and therefore denies same leaving Plaintiffs to their proofs.

17. Denied.

The Asserted Patents

18. NeuMoDx admits that U.S. Patent No. 8,273,308 (the "'308 Patent") entitled "Moving Microdroplets in a Microfluidic Device" issued on September 25, 2012. NeuMoDx denies it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 18, and therefore denies same leaving Plaintiffs to their proofs.

19. NeuMoDx admits that U.S. Patent No. 8,703,069 (the "'069 Patent"), entitled "Moving Microdroplets in a Microfluidic Device" issued on April 22, 2014. NeuMoDx denies

it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 19, and therefore denies same leaving Plaintiffs to their proofs.

20. NeuMoDx admits that U.S. Patent No. 7,998,708 (the “708 Patent”), entitled “Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel” issued on August 16, 2011. NeuMoDx denies it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 20, and therefore denies same leaving Plaintiffs to their proofs.

21. NeuMoDx admits that U.S. Patent No. 8,323,900 (the “900 Patent”), entitled “Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel” issued on December 4, 2012. NeuMoDx denies it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 21, and therefore denies same leaving Plaintiffs to their proofs.

22. NeuMoDx admits that U.S. Patent No. 8,415,103 (the “103 Patent”), entitled “Microfluidic Cartridge” issued on April 9, 2013. NeuMoDx denies it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 22, and therefore denies same leaving Plaintiffs to their proofs.

23. NeuMoDx admits that U.S. Patent No. 8,709,787 (the “787 Patent”), entitled “Microfluidic Cartridge and Method of Using Same” issued on April 29, 2014. NeuMoDx denies it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 23, and therefore denies same leaving Plaintiffs to their proofs.

24. NeuMoDx admits that U.S. Patent No. 10,494,663 (the “663 Patent”), entitled “Method for Processing Polynucleotide-Containing Samples” issued on December 3, 2019. NeuMoDx denies it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 24, and therefore denies same leaving Plaintiffs to their proofs.

25. NeuMoDx admits that U.S. Patent No. 10,364,456 (the “456 Patent”), entitled “Method for Processing Polynucleotide-Containing Samples” issued on July 30, 2019. NeuMoDx denies it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 25, and therefore denies same leaving Plaintiffs to their proofs.

26. NeuMoDx admits that U.S. Patent No. 10,443,088 (the “088 Patent”), entitled “Microfluidic Cartridge and Method of Using Same” issued on October 15, 2019. NeuMoDx denies it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 26, and therefore denies same leaving Plaintiffs to their proofs.

27. NeuMoDx admits that U.S. Patent No. 10,604,788 (the “788 Patent”), entitled “System for Processing Polynucleotide-Containing Samples” issued on March 31, 2020. NeuMoDx denies it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 27, and therefore denies same leaving Plaintiffs to their proofs.

28. NeuMoDx admits that U.S. Patent No. 10,625,261 (the “261 Patent”), entitled “Integrated Apparatus for Performing Nucleic Acid Extraction and Diagnostic Testing on Multiple Biological Samples” issued on April 29, 2014. NeuMoDx denies it was duly and

legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 28, and therefore denies same leaving Plaintiffs to their proofs.

29. NeuMoDx admits that U.S. Patent No. 10,625,262 (the “‘262 Patent”), entitled “Integrated Apparatus for Performing Nucleic Acid Extraction and Diagnostic Testing on Multiple Biological Samples” issued on April 21, 2020. NeuMoDx denies it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 29, and therefore denies same leaving Plaintiffs to their proofs.

30. NeuMoDx admits that U.S. Patent No. 10,632,466 (the “‘466 Patent”), entitled “Integrated Apparatus for Performing Nucleic Acid Extraction and Diagnostic Testing on Multiple Biological Samples” issued on April 28, 2020. NeuMoDx denies it was duly and legally issued. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 30, and therefore denies same leaving Plaintiffs to their proofs

31. NeuMoDx admits that Williams, Brahamasandra and other NeuMoDx employees are named as inventors on some of the Asserted Patents. NeuMoDx admits that as co-inventors of the ‘708 and ‘900 patents, Williams and Brahamasandra had knowledge of the ‘708 and ‘900 patents at some point after the ‘708 patent issued on August 16, 2011 and the ‘900 patent issued on December 4, 2012. The citation of some of the Asserted Patents during the prosecution of NeuMoDx’s patents, IPR2019-00488 and IPR2019-00490 proceedings and Exhibit 9 speak for themselves and therefore no response is required on allegations based upon those documents. NeuMoDx admits that it commissioned a review of patents no later than 2017

before making, using, selling or offering to sell NeuMoDx's molecular diagnostic products, which information was provided to BD on a confidential basis solely for the purpose of BD's consideration of NeuMoDx when NeuMoDx was being offered for sale, and which public disclosure by BD violates that obligation of confidentiality. NeuMoDx admits that BD included the '663, '456, '088 and '788 patents for the first time in disclosures dated April 13, 2020. NeuMoDx denies the remaining allegations in paragraph 31.

NEUMODX'S INFRINGING PRODUCTS

32. Denied.

33. NeuMoDx admits that it manufactures and sells molecular diagnostic systems, including NeuMoDx™ 288 Molecular System (Product Code 500100) and NeuMoDx™ 96 Molecular System (Product Code 50200). NeuMoDx admits that it also manufactures and sells, or has manufactured and/or sold, the instruments, consumables, accessories, test strips and reagents, listed in paragraph 33, although not all products have an accurate product code. NeuMoDx admits that its products are listed on its website. NeuMoDx denies the remaining allegations in paragraph 33.

34. NeuMoDx admits that its website links to videos showing operation of the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems. NeuMoDx admits that its website links to Vimeo hyperlinks <https://vimeo.com/281470603> and <https://vimeo.com/299307936>. NeuMoDx denies the remaining allegations in paragraph 34.

35. Admitted.

COUNT 1

(INFRINGEMENT OF THE '308 PATENT)

36. NeuMoDx incorporates and references its answers to the preceding paragraphs

of the Amended Complaint.

37. Denied.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

COUNT 2

(INFRINGEMENT OF THE '069 PATENT)

46. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Amended Complaint.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

COUNT 3

(INFRINGEMENT OF THE '708 PATENT)

54. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Amended Complaint

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

COUNT 4

(INFRINGEMENT OF THE '900 PATENT)

63. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Amended Complaint

64. Denied

65. Denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

COUNT 5 (INFRINGEMENT OF THE '103 PATENT)

74. NeuMoDx incorporates and references its answers to preceding paragraphs of the Amended Complaint

75. Denied.

76. Denied.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

COUNT 6 (INFRINGEMENT OF THE '787 PATENT)

82. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Amended Complaint.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

87. Denied.

88. Denied.

89. Denied.

COUNT 7 (INFRINGEMENT OF THE '663 PATENT)

90. NeuMoDx incorporates and references its answers to the preceding paragraphs of

the Complaint.

91. Denied.

92. Denied.

93. Denied.

94. Denied.

95. Denied.

96. Denied.

97. Denied.

98. Denied.

COUNT 8 (INFRINGEMENT OF THE '456 PATENT)

99. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Amended Complaint.

100. Denied.

101. Denied.

102. Denied.

103. Denied.

104. Denied.

105. Denied.

106. Denied.

107. Denied.

COUNT 9 (INFRINGEMENT OF THE '088 PATENT)

108. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Amended Complaint.

109. Denied.

110. Denied.

111. Denied.

112. Denied.

113. Denied.

114. Denied.

115. Denied.

116. Denied.

COUNT 10 (INFRINGEMENT OF THE '788 PATENT)

117. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Amended Complaint.

118. Denied.

119. Denied.

120. Denied.

121. Denied.

122. Denied.

123. Denied.

124. Denied.

125. Denied.

COUNT 11 (INFRINGEMENT OF THE '261 PATENT)

126. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Amended Complaint.

127. Denied.

128. Denied.

129. Denied.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

COUNT 12 (INFRINGEMENT OF THE '262 PATENT)

134. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Amended Complaint.

135. Denied.

136. Denied.

137. Denied.

138. Denied.

139. Denied.

140. Denied.

141. Denied.

COUNT 13 (INFRINGEMENT OF THE '466 PATENT)

142. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Amended Complaint.

143. Denied.

144. Denied.

145. Denied.

146. Denied.

147. Denied.

148. Denied.

149. Denied.

AFFIRMATIVE DEFENSES

First Affirmative Defense **(Invalidity)**

The ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents are invalid under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including for the failure to meet one or more of the requirements for patentability as specified in at least 35 U.S.C. §§ 101, 102, 103, and/or 112, as detailed below in NeuMoDx’s counterclaims.

Second Affirmative Defense **(Non-Infringement)**

NeuMoDx has not infringed, contributed to the infringement of, or induced the infringement of any valid claim of the asserted ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466, either directly or indirectly, literally or under the doctrine of equivalents, as detailed below in NeuMoDx’s counterclaims.

Third Affirmative Defense **(Equitable Estoppel/Acquiescence/Waiver/Unclean Hands)**

Plaintiffs are barred, in whole or in part, from recovering the relief sought in this action by the doctrine of equitable estoppel, acquiescence, waiver and/or unclean hands.

BD acquired HandyLab on November 19, 2009. Prior to the acquisition Jeff Williams was the CEO of HandyLab, and Sundaresh Brahmasandra was the Vice President of Product Development. Williams was not employed by BD after the acquisition but assisted with the transition for approximately one week at the request of BD and had a one year non-compete

agreement with BD. Brahmasandra remained with BD as an employee until March 2011. Brahmasandra's employment contract included a 2-year post-employment non-compete provision.

Williams continued his relationship with BD after the sale of HandyLab. In 2011, Williams, as CEO, facilitated the sale of Accuri Cytometers to BD. Also, in early 2011, and clear of his non-compete obligations, Williams contemplated a new company to pursue nucleic acid-based testing (molecular diagnostics) for higher throughput labs. Williams believed that an unmet need existed with a segment of customers in the molecular diagnostics market who desired a system that did not use unitized reagents and offered higher throughput, larger capacity, and more rapid turnaround time with better ease of use for medium to large hospital central laboratories and clinical reference labs. Williams formed Molecular Systems Corporation (MSC), the predecessor of NeuMoDx.

After completing his employment agreement with BD and BD's announcement that it would close the Ann Arbor facility, Brahmasandra left BD. Brahmasandra worked for another life-sciences company in Ann Arbor, and was subsequently invited to join MSC. However, Brahmasandra's non-compete agreement had not expired. Accordingly, in late 2011, Williams and Brahmasandra contacted senior executives at BD and shared Williams' intentions to actively pursue, with the support of venture capital, a startup nucleic acid testing systems company. Brahmasandra informed BD that he was interested in joining MSC, but that he was prevented from doing so because of the non-compete agreement with BD. Brahmasandra requested a waiver of his non-compete agreement to work with Williams at MSC to develop a nucleic acid-based system for performing rapid identification.

On December 21, 2011, BD, through a senior executive responsible for the diagnostics

business, granted Brahmasandra's request based upon Williams and Brahmasandra's "good track record." In return, BD asked for access to review MSC's technology for "future potential partnership interest." BD and Brahmasandra entered into an "Amendment to Employment Agreement" on February 23, 2012. BD acknowledged that "Employee (Brahmasandra) shall be permitted to engage in any activity relating to nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification contemplated by Molecular Systems Corporation", and that the "Proposed Business (MSC) shall not be deemed to Compete with or be Competitive with the Company (HandyLab) or any of its Affiliates for the purpose of this Agreement." The Amendment required Brahmasandra to use "commercially reasonable efforts" to schedule a meeting with "representatives of BD's exploratory technology group for the purpose of providing additional information about the Proposed Business, subject to the execution and delivery of a customary non-disclosure agreement... ."

Brahmasandra and MSC relied on BD representations, and Brahmasandra complied with his obligations. On several occasions during 2012 and 2013, NeuMoDx shared its business purposes, system architecture, technology, patents/patent applications and financing/financing plans with BD under confidentiality. In July 2013, NeuMoDx inquired with a senior BD executive about BD's interest in participating in a venture financing round of NeuMoDx. NeuMoDx provided a two-page summary of its system and technology and informed BD that NeuMoDx "had developed technology combining the best attributes of both integrated cartridge and microplate-based, liquid handling system, with the resulting platform to offer improved ease of use, lower costs, and higher performance compared to other nucleic acid testing systems."

After 2013, NeuMoDx met with representatives of BD at least annually at industry trade shows at which NeuMoDx provided BD with demonstrations of the NeuMoDx products and

answered questions about the technology. The last such meeting was at a trade show in April of 2019. BD explained to NeuMoDx that the meetings were intended to keep BD informed about NeuMoDx's technology in the event BD was interested in "partnership interests" or acquiring NeuMoDx. During the parties' meetings, NeuMoDx shared its technology, including confidential aspects of its technology, with BD. At no point from 2012 to December 2018 did BD ever suggest that any NeuMoDx product violates or infringes any BD patents, let alone the patents acquired by BD from HandyLab. Furthermore, on several occasions BD R&D personnel and executives commented on the uniqueness and novelty of the NeuMoDx products.

On December 21, 2018, BD's VP of Strategy & Business Development for BD Life Sciences contacted Williams to express concern regarding IPR petitions filed by Qiagen against BD's '708 and '900 patents. Williams assured BD that NeuMoDx was not involved in Qiagen's IPR filings. Williams described the care taken by NeuMoDx to ensure that its products do not infringe third party patents, including those belonging to BD and HandyLab given the relationship between BD/HandyLab and NeuMoDx. Williams invited BD to Ann Arbor to see NeuMoDx's products. On February 4, 2019, Williams and Brahmasandra met with two executives from BD at NeuMoDx's facility in Ann Arbor. The parties focused their discussions on the IPRs, NeuMoDx's products and NeuMoDx's detailed explanation as why its products do not violate the '708 and '900 patents subject to the IPR petitions. The parties discussed trying to arrive at a reasonable resolution, but BD needed time to discuss internally.

In April of 2019, NeuMoDx spoke with BD again at a trade show, but BD had no updates from the parties' February 4, 2019 meeting. No further communication between NeuMoDx and BD occurred until after BD filed the complaint against NeuMoDx.

Upon information and belief, after portraying the parties' meetings as a way to foster

potential collaborations between the parties’, and encouraging NeuMoDx to share its confidential product and technical information with BD to facilitate collaboration, BD is believed to have used NeuMoDx’s confidential against it to file the present Complaint.

Fourth Affirmative Defense
(Breach of Contract)

On February 23, 2012, BD and Brahmasandra entered into an “Amendment to Employment Agreement.” BD agreed that “Employee (Brahmasandra) shall be permitted to engage in any activity relating to nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification contemplated by Molecular Systems Corporation”, and that the “Proposed Business (MSC) shall not be deemed to Compete with or be Competitive with the Company (HandyLab) or any of its Affiliates for the purpose of this Agreement.” BD has now breached the Amended Agreement with Brahmasandra and MSC/NeuMoDx, the intended third party beneficiary of the Agreement, by suing NeuMoDx for the very nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification activity that BD agreed Brahmasandra and MSC/NeuMoDx could engage in, as detailed below in NeuMoDx’s counterclaims.

Fifth Affirmative Defense
(Lack of Notice)

The patent owner of the ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents failed to provide notice pursuant to 35 U.S.C. §287 prior to filing the original complaint. Plaintiffs failed to provide constructive notice of the ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents by marking any products covered by the patents. Likewise, Plaintiffs failed to provide actual notice of the ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents prior to filing the Complaint on

June 18, 2019. Therefore, Plaintiffs cannot recover damages for any alleged infringement that occurred prior to the filing of this case.

Sixth Affirmative Defense
(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim against NeuMoDx upon which relief can be granted.

Seventh Affirmative Defense
(Improper Inventorship)

The '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents are invalid under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including for the failure to identify the proper inventive entity as specified in at least 35 U.S.C. § 101 and pre-AIA 35 U.S.C. § 102(f). The '261, '262 and '466 patents improperly omit inventors of the claimed subject matter, including Sundaresh Brahmasandra, Elizabeth Boutt and Patrick Duffy. The '308, '069, '103, '787 patents improperly omit inventors of the claimed subject matter, including Sundaresh Brahmasandra and Jeff Williams. The '456, '088, '788, '663 patents improperly list inventors who are not believed to have contributed to the claimed subject matter, including Theodore Springer. The '708 and '900 patents improperly omit inventors of the claimed subject matter, including Kerry Wilson and Patrick Duffy and Nikhil Padke.

Eighth Affirmative Defense
(License)

Qiagen GmbH and HandyLab entered into a License and Supply Agreement on May 21, 2008, which was later amended on July 1, 2009 (the "HandyLab-Qiagen License Agreement"). The HandyLab Qiagen License Agreement granted certain rights to Qiagen.

[REDACTED] No later than September 18, 2020, NeuMoDx was acquired by Qiagen and became an affiliate of Qiagen.

Therefore, at least as early as September 18, 2020, NeuMoDx became licensed under the HandyLab-Qiagen License Agreement.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Thus, this clause granted a license under all HandyLab Patents.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This clause granted a license under all Handylab Patents.

Thus, NeuMoDx has a license under all the Asserted Patents at least as early as September 18, 2020. To the extent that any of NeuMoDx's Accused Products and/or activities are found to be covered by any claim of any of the Asserted Patents, such Accused Products or activity are covered by the HandyLab-Qiagen License Agreement (i.e., not infringing) since at least as early as September 18, 2020. Plaintiffs are therefore barred from recovering any damages for any such Accused Products and activities from at least that date forward.

COUNTERCLAIMS

PARTIES

1. Counterclaim Plaintiff NeuMoDx is corporation organized and existing under the

laws of Delaware, with its principal place of business at 1250 Eisenhower Place, Ann Arbor, Michigan 48108-3281.

2. On information and belief, Counterclaim Defendant Becton, Dickinson and Company (“Becton Dickinson”) is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 1 Becton Drive, Franklin Lakes, NJ 07417.

3. On information and belief, Counterclaim Defendant HandyLab is a wholly owned subsidiary of Becton Dickinson and a corporation organized and existing under the laws of Delaware, with at least some of the corporation’s business activities located in Franklin Lakes, NJ.

4. On information and belief, GeneOhm Sciences Canada, Inc. is wholly owned subsidiary of Becton Dickinson and a corporation organized and existing under the laws of Canada, with its principal place of business 2555 Boul du Parc-Technologique Québec G1P4S5 Canada (Counterclaim Defendants collectively referred to as “BD”).

JURISDICTION AND VENUE

5. This Court has subject matter of NeuMoDx’s counterclaims under at least 28 U.S.C. §§ 1331, 1332, 1338(a), 1367, 2201 and 2202.

6. Counterclaim Defendants are subject to personal jurisdiction in this judicial district because they availed themselves of the jurisdiction of this Court, and engaged in acts giving rise to this controversy in this district.

7. Venue is proper under 28 U.S.C. §§ 1391 and pursuant to Fed. R. Civ. P. 13 because BD filed this action in this district.

GENERAL ALLEGATIONS

COUNT I – DECLARATORY JUDGMENT OF NON-INFRINGEMENT

8. NeuMoDx incorporates by reference paragraphs 1-7 of its counterclaims and its affirmative defenses above as though fully set forth herein.

9. BD has alleged that NeuMoDx is infringing U.S. Patent Nos. 8,273,308; 8,703,069; 7,998,708; 8,323,900; 8,415,103; 8,709,787; 10,494,663; 10,364,456; 10,443,088; 10,604,788; 10,625,261; 10,625,262; and 10,632,466. The below paragraphs addressing non-infringement of the asserted patents are exemplary based upon information presently known, and are not intended to limit NeuMoDx's right to modify the below non-infringement positions or allege that it does not infringe other elements of the identified claims or any other claims of the asserted patents.

10. Based upon NeuMoDx's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claims 1, 18 and 19 of the '308 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '308 patent, including but not limited to:

[Claim 1] "a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the DNA manipulation zone when amplification of the sample occurs, wherein the only ingress to and egress from the DNA manipulation zone is through the first and second valves, and wherein the computer-controlled heat source is in thermal contact with the DNA manipulation zone"

[Claim 18] "a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the zone when amplification of the sample occurs in the zone, wherein the only ingress to and egress from the zone is through the first and second valves"

[Claim 19] "a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the DNA manipulation zone and to isolate and confine the sample to a region between the first and second valves accessible to the detector, wherein the only ingress to and egress from the region accessible to the detector is through the first and second valves"

11. Based upon NeuMoDx's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claim 1 of the '069 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '069 patent, including but not limited to:

[Claim 1] "closing the first valve and the second valve such that gas and liquid are prevented from flowing into or out of the DNA manipulation zone"

12. Based upon NeuMoDx's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claims 1 and 33 of the '708 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '708 patent, including but not limited to:

[Claim 1] "each PCR reaction zone comprising a separately controllable heat source thermally coupled thereto, wherein the heat source maintains a substantially uniform temperature throughout the PCR reaction zone and thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone"

[Claim 1] "a processor coupled to the detector and the heat source, configured to control heating of one or more PCR reaction zones by the heat sources"

[Claim 33] "introducing the plurality of samples into a multi-lane microfluidic cartridge, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples"

[Claim 33] amplifying polynucleotides contained with the plurality of samples in the PCR reaction zones while thermal cycling the PCR reaction zones, at least one PCR reaction zone separately thermally controllable from another PCR reaction zone

13. Based upon NeuMoDx's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claim 1, 7 and 20 of the '900 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and

every element, either literally or by application of the doctrine of equivalents, of any valid claim of the ‘900 patent, including but not limited to:

[Claim 1] “each PCR reaction zone comprising a separately controllable heat source thermally coupled thereto, wherein the heat source thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone and maintains a substantially uniform temperature throughout the PCR reaction zone during each cycle”

[Claim 1] “a processor coupled to the detector and the heat sources, configured to control heating of one or more PCR reaction zones by the heat sources”

[Claim 7] “a separately controllable heat source thermally coupled to each PCR reaction zone, wherein the heat source is configured to thermal cycle the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone and to maintain a substantially uniform temperature throughout the PCR reaction zone during each cycle”

[Claim 7] “a processor coupled to the detector and a plurality of the separately controllable heat sources, configured to control heating of one or more PCR reaction zones by one or more of the plurality of separately controllable heat sources”

[Claim 20] “introducing the plurality of samples into a plurality of multi-lane microfluidic cartridges, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples”

[Claim 20] “polynucleotides contained with the plurality of samples in the plurality of PCR reaction zones while thermal cycling the PCR reaction zones and maintaining a substantially uniform temperature throughout each PCR reaction zone during each cycle, at least one PCR reaction zone separately thermally controllable from another PCR reaction zone”

14. Based upon NeuMoDx’s ongoing investigation to date, NeuMoDx’s Accused Molecular Diagnostic Products do not infringe claim 1 and 15 of the ‘103 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the ‘103 patent including but not limited to:

[Claim 1] “placing the microfluidic cartridge in thermal communication with an array of independent heaters; and amplifying polynucleotides in the plurality of samples by independent application of successive temperature cycles to each sample”

[Claim 15] “introducing the plurality of samples in to a microfluidic cartridge, wherein the cartridge has a plurality of reaction chambers configured to permit thermal cycling of the plurality of samples independently of one another;

[Claim 15] “placing the microfluidic cartridge in thermal communication with an array of independent heaters; and amplifying polynucleotides contained within the plurality of samples, by application of successive temperature cycles independently to the reaction chambers”

15. Based upon NeuMoDx’s ongoing investigation to date, NeuMoDx’s Accused Molecular Diagnostic Products do not infringe claim 1, 9 and 10 of the ‘787 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the ‘787 patent, including but not limited to:

[Claim 1] “wherein the isolation effected by the first and the second set of microfluidic valves prevents movement of fluid into and out of the first and the second reaction chambers, wherein the first set of microfluidic valves comprises a first microfluidic valve spatially separated from the first inlet port and a second microfluidic valve spatially separated from the first outlet, and wherein the second set of microfluidic valves comprises a first microfluidic valve spatially separated from the second inlet port and a second microfluidic valve spatially separated from the second outlet, and wherein each of the first and second reaction chambers, the first and second inlet ports, the first and second outlets, and the first and second sets of microfluidic valves are all formed in the microfluidic substrate layer”

[Claim 9] “wherein the first valve and the second valve are configured to isolate the reaction chamber from the inlet and the vent to prevent movement of fluid into or out of the reaction chamber, wherein the first valve is spatially separated from the inlet and the second valve is spatially separated from the vent, wherein the reaction chamber, the first channel, and the second channel are formed in a first side of the microfluidic substrate, wherein the inlet and the vent are formed in a second side of the microfluidic substrate opposite the first side, and wherein the first valve in each of the plurality of sample lanes is operated independently of any other first valve”

[Claim 10] “introducing the plurality of samples into the microfluidic cartridge of claim 1, wherein the cartridge has a plurality of reaction chambers comprising the first reaction chamber and the second reaction chamber, the plurality of reaction chambers configured to permit thermal cycling of the plurality of samples independently of one another”

16. Based upon NeuMoDx’s ongoing investigation to date, NeuMoDx’s Accused

Molecular Diagnostic Products do not infringe claims 1, 14 or 18 of the ‘456 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the ‘456 patent, including but not limited to:

[Claim 1] “retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of binding particles comprising a poly-cationic substance , wherein the sample has a volume from 0.5 microliters to 3 milliliters”

[Claim 1] “wherein the first set of conditions includes a first pH of about 8.5 or less and a first temperature , wherein the first temperature is about 50° C”

[Claim 14] “retaining one or more polynucleotides from a sample on a plurality of binding particles under a first set of conditions, wherein a surface of one or more binding particles is modified with a poly-cationic material, wherein the sample has a volume from 0.5 microliters to 3 milliliters”

[Claim 14] “wherein the first set of conditions includes a first pH of 8.5 or less and a first temperature of about 50° C”

[Claim 14] “wherein the second set of conditions includes increasing the pH by at least three units by addition of a hydroxide solution and increasing the temperature by at least about 40° C. to a second temperature of at least about 90° C”

[Claim 18] “contacting the sample with a plurality of binding particles, the binding particles retaining one or more polynucleotides thereon at a first pH and a first temperature, wherein the sample has a volume from 0.5 microliters to 3 milliliters, wherein the first temperature is about 50° C., wherein a surface of one or more binding particles is modified with a poly-cationic polyimide or polyethyleneimine (PEI)”

[Claim 18] “contacting the binding particles with a basic hydroxide solution at a second pH and a second temperature, the second temperature greater than the first temperature, thereby releasing the polynucleotides from the plurality of binding particle, wherein the second temperature is between about 80° C. and about 100° C”.

17. Based upon NeuMoDx’s ongoing investigation to date, NeuMoDx’s Accused

Molecular Diagnostic Products do not infringe claims 1 and 13 of the ‘088 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and

every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '088 patent, including but not limited to:

[Claim 1] “retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of binding particles comprising a poly-cationic substance, wherein the sample has a volume from 0.5 microliters to 3 milliliters”

[Claim 13] “retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of binding particles comprising a poly-cationic substance; wherein the sample has a volume from 0.5 microliters to 3 milliliters”

18. Based upon NeuMoDx’s ongoing investigation to date, NeuMoDx’s Accused Molecular Diagnostic Products do not infringe claims 1, 22 and 40 of the '788 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '788 patent, including but not limited to:

[Claim 1] “a microfluidic device comprising substrate layers that define a microfluidic network, the microfluidic network comprising a first processing region, the microfluidic device further comprising a waste chamber downstream of the first processing region”

[Claim 1] “a lysing container located external to the substrate layers, wherein the lysing container is configured to receive the biological sample and configured to place the biological sample in contact with a lysing reagent to release polynucleotides from the biological sample into a lysate solution”

[Claim 1] “a plurality of magnetic binding particles disposed in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surfaces thereof, wherein the plurality of magnetic binding particles are configured to retain at least a portion of the polynucleotides on the surface thereof in the lysate solution at a pH of 8.5 or less”

[Claim 1] “a second processing region comprising PCR reagents, the second processing region configured to receive the eluate solution containing polynucleotides and configured to place the eluate solution in contact with PCR reagents to form a PCR-ready solution”

[Claim 22] “plurality of magnetic binding particles disposed in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surfaces thereof, the lysing container configured to place the biological sample in contact with a lysing reagent to release polynucleotides from the biological sample into a lysate solution, the plurality of magnetic binding particles configured to retain at least a portion of the polynucleotides on the surface thereof at a pH of about 8.5 or less in the lysate solution”

[Claim 22] “substrate layers defining a microfluidic network that comprises a plurality of microfluidic components including a first processing region, wherein the first processing region is configured to receive, from the lysing container, the lysate solution and the plurality of magnetic binding particles retaining the polynucleotides on the surface thereof; wherein the lysing container is located external to the substrate layers defining the microfluidic network”

[Claim 22] wherein the plurality of magnetic binding particles are configured to release at least a portion of the polynucleotides into an eluate solution when in the presence of the release solution in the first processing region and when heat is applied by a heat source of the plurality of heat sources to the lysate solution and the plurality of magnetic binding particles in the first processing region”

[Claim 22] “a second processing region comprising PCR reagents and configured to receive the eluate solution containing the eluted polynucleotides to reconstitute the PCR reagents and form a PCR-ready solution”

[Claim 40] “a microfluidic network disposed in a plurality of substrate layers, wherein the microfluidic network comprises a processing region and a detection region”

[Claim 40] “a lysing container located external to the substrate layers, wherein the lysing container is configured to receive the biological sample and configured to place the biological sample in contact with a lysing reagent to release polynucleotides from the biological sample into a lysate solution”

[Claim 40] “a plurality of magnetic binding particles disposed in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surfaces thereof, wherein the plurality of magnetic binding particles are configured to retain at least a portion of the polynucleotides on the surface thereof in the lysate solution at a pH of about 8.5 or less”

19. Based upon NeuMoDx’s ongoing investigation to date, NeuMoDx’s Accused Molecular Diagnostic Products do not infringe claim 1 and 27 of the ‘663 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the

‘663 patent, including but not limited to:

[Claim 1] “heating the biological sample in the lysing container to a first temperature between about 30° C. and about 50° C., wherein the polynucleotides are extracted from the biological sample into a lysate solution”

[Claim 1] “contacting the polynucleotides with a plurality of magnetic binding particles in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surface thereof, wherein at least a portion of the polynucleotides are retained on the plurality of magnetic binding particles in the lysate solution”

[Claim 1] “transferring the lysate solution containing the plurality of magnetic binding particles into a first processing region, wherein the first processing region is within a microfluidic network in the system, and wherein the lysing container is located external to the microfluidic network”

[Claim 1] “transferring the eluate solution containing polynucleotides to a second processing region in the system, wherein the eluate solution reconstitutes PCR reagents contained in the second processing region to form a PCR-ready solution”

[Claim 27] “heating the biological sample in the lysing container to a first temperature of about 60° C., wherein the polynucleotides are extracted from the biological sample into a lysate solution”

[Claim 27] “contacting the polynucleotides with a plurality of magnetic binding particles in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surface thereof, wherein at least a portion of the polynucleotides are retained on the plurality of magnetic binding particles in the lysate solution”

[Claim 27] “transferring the lysate solution containing the plurality of magnetic binding particles into a first processing region, wherein the first processing region is within a microfluidic network in the system; and wherein the lysing container is outside of the microfluidic network”

[Claim 27] “transferring the eluate solution containing polynucleotides to a second processing region in the system, wherein the eluate solution reconstitutes PCR reagents contained in the second processing region to form a PCR-ready solution”

20. Based upon NeuMoDx’s ongoing investigation to date, NeuMoDx’s Accused Molecular Diagnostic Products do not infringe claims 1 and 22 of the ‘261 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and

every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '261 patent, including but not limited to:

[Claim 1] “a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples”

[Claim 1] “a bay configured to removably receive a housing comprising a plurality of process chambers that are maintained at a same height relative to one another when the housing is received in the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members configured to receive the housing in a single orientation when the housing is received in the bay”

[Claim 1] “the first module further comprising a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members further configured to align the plurality of process chambers with the magnetic separator when the housing is received in the bay”

[Claim 1] “the first module further comprising a heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the heating assembly configured to heat a solution in the plurality of process chambers to between 50° C. and 85° C., the one or more complementary registration members configured to align the plurality of process chambers with the heater assembly when the housing is received in the bay”

[Claim 22] “a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples, the first module comprising: a bay configured to removably receive a housing comprising a plurality of process chambers that are maintained at a same height relative to one another when the housing is received in the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members configured to receive the housing in a single orientation when the housing is received in the bay”

[Claim 22] “a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members further configured to align the plurality of process chambers with the magnetic separator when the housing is received in the bay”

[Claim 22] “a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members further configured to align the plurality of process chambers with the magnetic separator when the housing is received in the bay”

21. Based upon NeuMoDx’s ongoing investigation to date, NeuMoDx’s Accused Molecular Diagnostic Products do not infringe claim 1 of the ‘262 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the ‘262 patent, including but not limited to:

[Claim 1] “a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples, the first module comprising: a plurality of sample tubes in the first module, each sample tube configured to accept a nucleic acid-containing sample of the plurality of nucleic-acid containing samples”

[Claim 1] “a plurality of process chambers in the first module, wherein a process chamber of the plurality of process chambers is spatially separate from, and corresponds to, a sample tube of the plurality of sample tubes, the plurality of process chambers maintained at a same height relative to one another in the first module”

[Claim 1] “a magnetic separator configured to apply a magnetic force to at least one process chamber of the plurality of process chambers in the first module”

22. Based upon NeuMoDx’s ongoing investigation to date, NeuMoDx’s Accused Molecular Diagnostic Products do not infringe claims 1 and 23 of the ‘466 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the ‘466 patent, including but not limited to:

[Claim 1] “extracting nucleic acids from the plurality of nucleic acid-containing samples in a first module and amplifying the nucleic acid extracted from the plurality of nucleic acid-containing samples simultaneously in a second module using a system comprising a liquid dispenser and a bay, the first module comprising a magnetic separator and a heating assembly, wherein extracting the nucleic acids comprises”

[Claim 1] “removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the magnetic separator when the housing is received in the bay, the heating assembly of the first module positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the heater assembly when the housing is received in the bay”

[Claim 1] “dispensing, using the liquid dispenser, at least a portion of the plurality of nucleic acid-containing samples and a plurality of magnetic binding particles into the plurality of process chambers when the housing is received in the bay”

[Claim 1] “moving the liquid dispenser between the plurality of nucleic acid-containing samples and the plurality of process chambers when the housing is received in the bay”

[Claim 1] “dispensing the nucleic acid extracted from the plurality of nucleic-acid containing samples into the second module”

[Claim 23] “extracting nucleic acids from the plurality of nucleic acid-containing samples in a first module using a system comprising a liquid dispenser, the first module comprising a bay, a magnetic separator, and a heating assembly, wherein extracting the nucleic acids comprises”

[Claim 23] “removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the magnetic separator when the housing is received in the bay, the heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater

assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the heater assembly when the housing is received in the bay”

[Claim 23] “dispensing, using the liquid dispenser, at least a portion of the plurality of nucleic acid-containing samples and a plurality of magnetic binding particles into the plurality of process chambers when the housing is received in the bay”

[Claim 23] “moving the liquid dispenser between the plurality of nucleic acid-containing samples and the plurality of process chambers when the housing is received in the bay”

[Claim 23] “dispensing the nucleic acid extracted from the plurality of nucleic-acid containing samples into a second module, the second module configured to receive a multi-lane microfluidic cartridge configured to simultaneously amplify the nucleic acid extracted from the plurality of nucleic acid-containing samples”

23. NeuMoDx’s Accused Molecular Diagnostic Products also do not infringe any claims of the ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents, either directly or indirectly, because the ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents are invalid and thus cannot be infringed, for the reasons set forth in the following paragraphs contained in Count 2 of NeuMoDx’s Counterclaim

24. By reason of BD’s charges of patent infringement, and NeuMoDx’s denial of those charges, there exists a justiciable controversy between BD and NeuMoDx with respect to BD’s assertion of infringement of the ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents and NeuMoDx’s denial thereof.

25. NeuMoDx is entitled to a judgment under Rule 57 of the Federal Rules of Civil Procedure and 28 U.S.C. § 2201 declaring that NeuMoDx is not infringing and has not infringed the ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents and granting to NeuMoDx all other declaratory relief to which it may be entitled.

COUNT 2 – DECLARATORY JUDGMENT OF INVALIDITY

26. NeuMoDx incorporates by reference the above paragraphs of its counterclaims

and its affirmative defenses above as though fully set forth herein.

27. By implication of BD's allegations that NeuMoDx infringes one or more claims of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents, BD contends that the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents are valid and enforceable.

28. NeuMoDx alleges that the claims of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents are invalid because they fail to comply with one or more requirements of the Patent Laws of the United States, 35 U.S.C. §1 et seq., including without limitation, §§ 101, 102, 103 or 112, as the claims of the patents are anticipated, obvious and/or indefinite, and that there is prior art and other evidence that anticipates or renders obvious the claims of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents.

29. Based upon NeuMoDx's ongoing investigation, the claims of the '708 patent are invalid in view of at least the prior art raised in IPR2019-00488 filed by Qiagen North American Holdings, Inc. against HandyLab, Inc, including but not limited to Zou I, U.S. Patent No. 6,509,186; McNeely, U.S. Patent App. Pub. No. US 2004/0037739; Pease, U.S. Patent App. Pub. No. US2004/0151629; Hsieh, U.S. Patent No. 7,122,799; Zou II, U.S. Patent No. 6,762,049; Duong, WO 01/54813; Chow, U.S. Patent No. 5,955,028; and Wilding U.S. Patent Publication No. 2003/0199081. The Patent Trial and Appeals Board ("PTAB") instituted trial on Claims 1-33 in a decision dated July 16, 2019, finding that "Petitioner has established a reasonable likelihood of prevailing with respect to claims 1-6, 9, 10, 18-20, 23-25, 28 and 33 of the '708 patent" and with respect to dependent claims 7, 8, 11-17, 21, 22, 26, 27 and 29.

30. Based upon NeuMoDx's ongoing investigation, the claims of the '900 patent are

invalid in view of at least the prior art raised in IPR2019-00490 filed by Qiagen North American Holdings, Inc. against HandyLab, Inc, including but not limited to Zou I, U.S. Patent No. 6,509,186; McNeely, U.S. Patent App. Pub. No. US 2004/0037739; Pourahmadi, U.S. Patent App. Pub. US 2002/0055167; Zou II, U.S. Patent No. 6,762,049; Duong, WO 01/54813; Chow, U.S. Patent No. 5,955,028; and Wilding U.S. Patent Publication No. 2003/0199081. The Patent Trial and Appeals Board (“PTAB”) instituted trial on Claims 1-22 in a decision dated July 16, 2019, finding that “Petitioner has demonstrated a reasonable likelihood that it will prevail on its challenge to at least one of the claims of the ‘900 patent.”

31. Based upon NeuMoDx’s ongoing investigation to date, the claims of the ‘308 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references raised in IPR2020-01083 and IPR2020-0191 filed by NeuMoDx against HandyLab, Inc., including but not limited to: Pourahmadi, WO 99/33559; Chang, WO 98/38487; Mian, WO 97/21090; Anderson, U.S. Patent No. 6,168,948; Northrup, WO 94/05414; and Southgate WO 97/27324; the other prior art references identified in the IPR2020-01083 and IPR2020-0191 petitions; Neukermans, WO 97/22825; Lipshultz, U.S. Patent No. 5,856,74; Wilding, U.S. Patent No. 5,955,029; McNeely WO 00/22436; Nelson, U.S. Patent No. 6,007,690; Burns WO 99/01688; Wilding U.S. Patent Publication No. 2003/0199081; and Handique WO 00/17093.

32. Based upon NeuMoDx’s ongoing investigation to date, the claims of the ‘069 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references raised in IPR2020-01095 and IPR2020-01100 filed by NeuMoDx against HandyLab, Inc., including but not limited to: Pourahmadi, WO 99/33559; Chang, WO 98/38487; Mian, WO 97/21090; Anderson, U.S. Patent

No. 6,168,948; Northrup, WO 94/05414; and Southgate WO 97/27324; the other prior art references identified in the IPR2020-01095 and IPR2020-01100 petitions; Neukermans, WO 97/22825; Lipshultz, U.S. Patent No. 5,856,74; Wilding, U.S. Patent No. 5,955,029; McNeely WO 00/22436; Nelson, U.S. Patent No. 6,007,690; Burns WO 99/01688; Wilding U.S. Patent Publication No. 2003/0199081; and Handique WO 00/17093.

33. Based upon NeuMoDx's ongoing investigation to date, the claims of the '103 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references raised in IPR2020-01133 and IPR2020-01136 filed by NeuMoDx against HandyLab, Inc., including but not limited to: Handique, U.S. Patent Publication No. 2007/0292941; Handique, U.S. Provisional Appl. No. 60/859,284; Ganesan, U.S. Patent Publication No. 2005/0084424; Jensen, U.S. Patent Publication No. 2006/0246493; Kellogg, WO 00/78455; Yoon, U.S. Patent Publication No. US 2005/0112754; Handique, U.S. Provisional Appl. No. 60/786,007; Kellogg, WO 00/78455; Mian, U.S. Patent No. 6,319,469; Zou I, U.S. Patent No. 6,509,186; Zou II, U.S. Patent No. 6,762,049; the other prior art references identified in the IPR2020-01133 and IPR2020-01136 petitions; Kellogg, WO 00/78455; Mian, U.S. Patent No. 6,319,469; Zou I, U.S. Patent No. 6,509,186; Mian, WO 97/21090; McNeely, U.S. Patent App. Pub. No. US 2004/0037739; Pease, U.S. Patent App. Pub. No. US2004/0151629; Hsieh, U.S. Patent No. 7,122,799; Zou II, U.S. Patent No. 6,762,049; Duong, WO 01/54813; Chow, U.S. Patent No. 5,955,028; Wilding U.S. Patent Publication No. 2003/0199081; and Pourahmadi, U.S. Patent App. Pub. US 2002/0055167.

34. Based upon NeuMoDx's ongoing investigation to date, the claims of the '787 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references raised in IPR2020-01132 and

IPR2020-01137 filed by NeuMoDx against HandyLab, Inc., including but not limited to: Handique, U.S. Provisional Appl. No. 60/859,284; Ganesan, U.S. Patent Publication No. 2005/0084424; Jensen, U.S. Patent Publication No. 2006/0246493; Björnson, U.S. Patent No. 6,827,906; Kellogg, WO 00/78455; Yoon, U.S. Patent Publication No. US 2005/0112754; Handique, U.S. Provisional Appl. No. 60/786,007; Kellogg, WO 00/78455; Mian, U.S. Patent No. 6,319,469; Zou I, U.S. Patent No. 6,509,186; Zou II, U.S. Patent No. 6,762,049; the other prior art references identified in the IPR2020-01132 and IPR2020-01137 petitions; Mian, WO 97/21090; McNeely, U.S. Patent App. Pub. No. US 2004/0037739; Pease, U.S. Patent App. Pub. No. US2004/0151629; Hsieh, U.S. Patent No. 7,122,799; Duong, WO 01/54813; Chow, U.S. Patent No. 5,955,028; Wilding U.S. Patent Publication No. 2003/0199081; and Pourahmadi, U.S. Patent App. Pub. US 2002/0055167.

35. Based upon NeuMoDx's ongoing investigation to date, the claims of the '456 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including: Backus, EP 0707077; Baker, U.S. Patent No. 6,914,137; Baker, WO 00/75623; and Deggerdal, US 2006/0058519.

36. Based upon NeuMoDx's ongoing investigation to date, the claims of the '088 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including: Backus, EP 0707077; Baker, U.S. Patent No. 6,914,137; Baker, WO 00/75623; and Deggerdal, US 2006/0058519.

37. Based upon NeuMoDx's ongoing investigation to date, the claims of the '788 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including: Backus, EP 0707077; Baker, U.S. Patent No. 6,914,137; Baker, WO 00/75623; and Deggerdal, US 2006/0058519.

38. Based upon NeuMoDx's ongoing investigation to date, the claims of the '663 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including: Backus, EP 0707077; Baker, U.S. Patent No. 6,914,137; Baker, WO 00/75623; and Deggerdal, US 2006/0058519.

39. Based upon NeuMoDx's ongoing investigation to date, the claims of the '261 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including: Southgate, U.S. Patent No. 5,863,801; Southgate, U.S. Patent No. 5,863,502; Southgate WO 97/27324; McBride, WO 97/16835; Yoo, WO 2006/118420; Yoo, WO 2003/080868; Pollack, WO 2007/120240; Pollack, WO 2007/120241; Bienhaus, U.S. Patent No. 6,117,398; Okada, JPH 09304385; Ammann, U.S. Patent No. 7,118,892; Ammann, US 2006/0003373; Ammann, US 2005/0130198; Ammann, US 2005/0239127; and Ammann, US 2005/0266489.

40. Based upon NeuMoDx's ongoing investigation to date, the claims of the '262 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including: Southgate, U.S. Patent No. 5,863,801; Southgate, U.S. Patent No. 5,863,502; Southgate WO 97/27324; McBride, WO 97/16835; Yoo, WO 2006/118420; Yoo, WO 2003/080868; Pollack, WO 2007/120240; Pollack, WO 2007/120241; Bienhaus, U.S. Patent No. 6,117,398; Okada, JPH 09304385; Ammann, U.S. Patent No. 7,118,892; Ammann, US 2006/0003373; Ammann, US 2005/0130198; Ammann, US 2005/0239127; and Ammann, US 2005/0266489.

41. Based upon NeuMoDx's ongoing investigation to date, the claims of the '466 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including: Southgate, U.S. Patent

No. 5863,801; Southgate, U.S. Patent No. 5,863,502; Southgate WO 97/27324; McBride, WO 97/16835; Yoo, WO 2006/118420; Yoo, WO 2003/080868; Pollack, WO 2007/120240; Pollack, WO 2007/120241; Bienhaus, U.S. Patent No. 6,117,398; Okada, JPH 09304385; Ammann, U.S. Patent No. 7,118,892; Ammann, US 2006/0003373; Ammann, US 2005/0130198; Ammann, US 2005/0239127; and Ammann, US 2005/0266489.

42. An actual and justiciable controversy exists between BD and NeuMoDx regarding the invalidity of the ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents.

43. NeuMoDx is entitled to a judgment under Rule 57 of the Federal Rules of Civil Procedure and 28 U.S.C. § 2201 declaring that the claims of the ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents are invalid.

COUNT III – BREACH OF CONTRACT

44. NeuMoDx incorporates by reference the above paragraphs of its counterclaims and its affirmative defenses above as though fully set forth herein.

45. In late 2011, Williams and Brahmasandra contacted senior executives at BD and shared Williams’ intentions to actively pursue, with the support of venture capital, a startup nucleic acid testing systems company.

46. Brahmasandra informed BD that he was interested in joining MSC, but that he was prevented from doing so because of the non-compete agreement with BD.

47. Brahmasandra requested a waiver of his non-compete agreement to work with Williams at MSC to develop a nucleic acid-based system for performing rapid identification.

48. On February 23, 2012, BD and Brahmasandra entered into an “Amendment to Employment Agreement.” BD agreed that “Employee (Brahmasandra) shall be permitted to

engage in any activity relating to nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification contemplated by Molecular Systems Corporation.”

49. BD also agreed that the “Proposed Business (MSC) shall not be deemed to Compete with or be Competitive with the Company (HandyLab) or any of its Affiliates for the purpose of this Agreement.”

50. MSC is an intended third party beneficiary of the February 23, 2012 Agreement.

51. There was consideration for the Amended Agreement. Brahmasandra was required to “use “commercially reasonable efforts” to schedule a meeting with “representatives of BD’s exploratory technology group for the purpose of providing additional information about the Proposed Business, subject to the execution and delivery of a customary non-disclosure agreement...”.

52. Brahmasandra complied with his obligations. On several occasions during 2012 and 2013, MSC, which changed its name in 2012 to NeuMoDx, shared its business purposes, system architecture, technology, patents/patent applications and financing/financing plans with BD.

53. In July 2013, NeuMoDx inquired with a senior BD executive about BD’s interest in participating in a venture financing round of NeuMoDx. NeuMoDx provided a two-page summary of its system and technology and informed BD that NeuMoDx “had developed technology combining the best attributes of both integrated cartridge and microplate-based, liquid handling system, with the resulting platform to offer improved ease of use, lower costs, and higher performance compared to other nucleic acid testing systems.”

54. After 2013, NeuMoDx met with representatives of BD at least annually at industry trade shows at which NeuMoDx provided BD with demonstrations of the NeuMoDx

products and answered questions about the technology. During the parties' meetings, NeuMoDx shared its technology, including confidential aspects of its technology, with BD.

55. BD has now breached the Amended Agreement with Brahmasandra and MSC/NeuMoDx, the intended third party beneficiary of the Agreement, by suing NeuMoDx for the very nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification activity that BD agreed Brahmasandra and MSC/NeuMoDx could engage in.

56. NeuMoDx has been harmed and suffered damages as a direct and proximate result of BD's breach of contract, including but limited to the time, resources, attorney's fees, costs and expenses incurred in defending the present lawsuit filed by BD against NeuMoDx, as well as actual damages, reputational damages and lost opportunities resulting from BD's breach.

RESERVATIONS OF RIGHTS

The above affirmative defenses and counterclaims are based upon incomplete information because (i) NeuMoDx has not yet been afforded any significant discovery in this case; and (ii) NeuMoDx's discovery and investigation of the claims, counterclaims and defenses in this action are continuing. Therefore, NeuMoDx reserves the right to supplement and/or amend such defenses and/or counterclaims if and when further information becomes available.

PRAYER FOR RELIEF

WHEREFORE, NeuMoDx prays for entry of a judgment:

1. Dismissing the Complaint with prejudice;
2. Declaring that NeuMoDx is not infringing, and has not infringed, directly, contributorily, or by inducement, any claim of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents, either literally or under the doctrine of equivalents;

3. Declaring that the claims of the ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents are invalid under 35 U.S.C. §§ 102, 103, and /or 112;

4. Declaring that this case is “exceptional” under 35 U.S.C. § 285 and awarding NeuMoDx its reasonable attorney’s fees and costs;

5. Enjoining BD from enforcing the ‘308, ‘069, ‘708, ‘900, ‘103, ‘787, ‘456, ‘088, ‘788, ‘663, ‘261, ‘262 and ‘466 patents against NeuMoDx or any of NeuMoDx’s current or future customers;

6. Declaring that BD has breached the February 23, 2012, BD “Amendment to Employment Agreement” by filing the present lawsuit;

7. Awarding NeuMoDx damages for BD’s breach of February 23, 2012, BD “Amendment to Employment Agreement”, including but not limited to the time, resources, attorney’s fees, costs and expenses incurred in defending the present lawsuit filed by BD against NeuMoDx, as well as actual damages, reputational damages, lost opportunities resulting from BD’s breach, and pre and post-judgment interest.

8. Awarding to NeuMoDx any further necessary and proper relief under 28 U.S.C. § 2202;

9. Directing BD to pay all costs and expenses incurred by NeuMoDx in this action, including reasonable attorneys’ fees; and

10. Such other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, NeuMoDx hereby demand a trial by jury on all issues so triable.

Dated: December 11, 2020

Respectfully submitted,

Of Counsel:

FARNAN LLP

James K. Cleland
Michael Spink
Keith Weiss
Dickinson Wright PLLC
350 S. Main Street, Suite 300
Ann Arbor, Michigan 48104
Tel. 734-436-7356
jcleland@dickinson-wright.com

/s/ Brian E. Farnan
Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 N. Market Str., 12th Floor
Wilmington, DE 19801
Tel: (302) 777-0300
Fax: (302) 777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Alan G. Carlson
Gary J. Speier
Samuel T. Lockner
Jonathan D. Carpenter
Alexandra J. Olson
Peter M. Kohlhepp
CARLSON, CASPERS, VANDENBURGH &
LINDQUIST, P.A.
225 South Sixth Street, Suite 4200
Minneapolis, MN 55402
Telephone: (612) 436-9600
Facsimile: (612) 436-9605

Attorneys for Defendant